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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/444,459	11/22/1999	Bruce M. Cameron SR.	72874.0113	8685

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EXAMINER

LEARY, LOUISE N

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 04/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/444,459

Applicant(s)

CAMERON ET AL.

Examiner

Louise N. Leary

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-25, 56, 60-67, 69, 70, 76, 78 and 81-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21-25 is/are allowed.
- 6) ☒ Claim(s) 56, 60-62, 67, 76 and 82-85 is/are rejected.
- 7) ☒ Claim(s) 63-66, 69, 70, 78 and 81 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 December 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

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1. Claims 21-25, 56, 60-67, 69-70, 76, 78 and 81-85 are pending in this application.

Claims 1-20, 26-55, 57-59, 68, 71-75, 77, 79-80 have been canceled per applicant's request.

2. The drawings filed December 2, 2002 are accepted by the examiner.

3. The rejection of claim 70 under 35 USC 112, second paragraph has been withdrawn in view of the amendment filed December 2, 2002.

4. The examiner has carefully considered applicant's arguments presented in the amendment filed December 2, 2002. However, applicant's arguments were not persuasive and the rejection of claims 56, 60-62, 67, and 76 under 35 USC 102(b) as anticipated by or, in the alternative, under 35 USC 103(a) as obvious over Cook (US 3,928,594) has been maintained for reasons of record. Newly added claims 82-85 have also been rejected under 35 USC 102(b) as anticipated by or, in the alternative, under 35 USC 103(a) as obvious over Cook (US 3,928,594).

5. Applicant's arguments filed December 2, 2002 have been fully considered but they are not persuasive.

At page 10 of the amendment filed December 2, 2002, applicants have argued "One skilled in the art at the time the present application was filed and at the time Cook was filed would not assume that "observing" a patient involves evaluation of pain intensity, especially in a disease such as multiple sclerosis where many symptoms are indicative of the disease state." It is noted, however, that Cook discloses a method for diagnosing the intensity of pain in a patient comprising determining the amount of cholinesterase in a biological sample from the patient. See this entire document. Also regarding applicant's statements at page 11 of the amendment, "In light of the above remarks and Applicant's previous arguments, Applicants assert that Cook fails to disclose or suggest any objective measurements of biological marker for pain.", the examiner respectfully disagrees. It is noted that Cook discloses methods for treating the symptoms and signs associated with demyelinating processes or other conditions in man characterized by defective neural transmission with an acetylcholine-cholinesterase imbalance

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due to relative decrease in cholinesterase activity. Cook especially describes multiple sclerosis as an example of a demyelinating disease. Note the Abstract and column 2, lines 34-66. Cook also discloses methods for administering pharmaceutical compositions to alleviate pain associated with cholinesterase imbalance(s) in patients with pathological central nervous system (i.e., brain and spine) or spinal cord conditions. Note column 5, lines 2-29 and column 6, lines 1-28. Further, the examiner disagrees with applicant's assertion that one skilled in this art before this invention was made would not have been able to objectively evaluate pain in a patient with multiple sclerosis or other representative neurological disorders within the scope of the Cook et al reference. Therefore, for the reasons stated above the rejection of the claims has been maintained.

6. Claims 63-66, 69-70, 78 and 81 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Claims 21-25 are allowable over the prior art of record.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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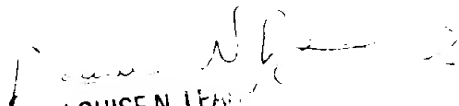
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is (703) 308-3533. The examiner can normally be reached on Monday to Friday from 10 to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703)308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1235.

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LOUISE N. LEARY
PRIMARY EXAMINER

April 7, 2003